UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/734,150	12/15/2003	Frank E. Blondino	033018-121	2098

21839 7590 06/14/2007

BUCHANAN, INGERSOLL & ROONEY PC
POST OFFICE BOX 1404
ALEXANDRIA, VA 22313-1404

EXAMINER	
HAGHIGHATIAN, MINA	
ART UNIT	PAPER NUMBER
1616	

MAIL DATE	DELIVERY MODE
06/14/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/734,150	BLONDINO ET AL.	
	Examiner	Art Unit	
	Mina Haghighatian	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 March 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16 and 18-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *15-16, 19, 23-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of Amendments and Remarks filed on 03/27/07. Claims 15, 16, 19, 23 and 25-30 have been amended. Claim 17 has been cancelled and no new claims have been added. Claims 1-16 and 18-30 are pending of which claims 1-14, 18 and 20-22 have been withdrawn. Accordingly, claims **15-16, 19, 23-30** are under consideration.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 26 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 26 is vague for reciting the term "derivatives thereof". The specification does not adequately recite derivatives of active agents such as buprenorphine.

Claim Rejections - 35 USC § 102

The rejection of claims 15-17, 19, 23-24, 26-30 under 35 U.S.C. 102(e) as being anticipated by Rabinowitz et al (US20040202617) is withdrawn in light of the amendments.

Claim Rejections - 35 USC § 103

The rejection of claims 15, 17, 19, 23-30 under 35 U.S.C. 103(a) as being unpatentable over Hodges et al (6,682,716) is withdrawn in light of the amendments.

Claims 15, 17, 19, 23-30 rejected under 35 U.S.C. 103(a) as being unpatentable over Nguyen et al (7,040,314) is withdrawn in light of Applicant stating common assignment.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims **15-16, 19, 23-30** are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 18-36 of U.S. Patent No.

7,040,314. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims would have been obvious over the reference claims. Here, both the instant claims and the reference claims are drawn to a method of generating an aerosol comprising supplying a liquid aerosol formulation to a flow passage and heating the liquid to form a vapor. The active agents suitable for the said method are "a thermally stable active agent". The difference between the two applications is that in the instant claims the active agent is buprenorphine, while the reference claims have a selection of many active agents. Specification lists buprenorphine as a suitable species.

Claims **15-16, 19, 23-30 are** rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 26-41 of U.S. Patent No. 5,743,251 in view of Rabinowitz et al (US20040202617). Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims would have been obvious over the reference claims in view of Rabinowitz et al (US20040202617). Here, both the instant claims and the reference claims are drawn to a method of generating an aerosol comprising supplying a liquid aerosol formulation to a flow passage and heating the liquid to form a vapor. The active agents suitable for the said method are "a thermally stable active agent". The difference between the two applications is that in the instant claims the active agent is buprenorphine, while the reference claims recite "a material" Rabinowitz teaches delivery of drugs through an inhalation route. Specifically, an aerosol containing active agents that are used in

inhalation therapy is disclosed. Also a method of delivery is disclosed which method comprises heating a thin layer of an active agent, on a solid support, to from a vapor, and passing air through the heated vapor to produce aerosol particles having less than 5% degradation products. It is disclosed that typically, the aerosol particles have a mass median aerodynamic diameter (MMAD) of less than 5 microns. Preferably the particles have an MMAD of less than 3, less than 2 or less than 1 micron. Suitable active agents for the said aerosol vapor formulation include **buprenorphine** or its salts. The formulations may contain one or more excipients such as propylene glycol, glycerol, ethanol, methanol, etc.

Claims **15-16, 19, 23-30 are** rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims of U.S. Patent No. 7,128,067 in view of Rabinowitz et al (US20040202617). Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims would have been obvious over the reference claims in view of Rabinowitz et al (US20040202617). Here, both the instant claims and the reference claims are drawn to a method of generating an aerosol comprising supplying a liquid aerosol formulation to a flow passage and heating the liquid to form a vapor. The active agents suitable for the said method are "a thermally stable active agent". The difference between the two applications is that in the instant claims the active agent is buprenorphine, while the reference claims recite "a material". Rabinowitz teaches delivery of drugs through an inhalation route. Specifically, an aerosol containing active agents that are used in

inhalation therapy is disclosed. Also a method of delivery is disclosed which method comprises heating a thin layer of an active agent, on a solid support, to from a vapor, and passing air through the heated vapor to produce aerosol particles having less than 5% degradation products. It is disclosed that typically, the aerosol particles have a mass median aerodynamic diameter (MMAD) of less than 5 microns. Preferably the particles have an MMAD of less than 3, less than 2 or less than 1 micron. Suitable active agents for the said aerosol vapor formulation include **buprenorphine** or its salts. The formulations may contain one or more excipients such as propylene glycol, glycerol, ethanol, methanol, etc.

Claims **15-16, 19, 23-30 are** rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims of U.S. Patent Nos. 7,173,222; 7,167,776; 7,163,014; 7,147,170; 7,117,867; 6,923,179; 6,854,461; 7,077,130; 6,883,516; 6,799,572; 6,766,220; 6,701,922; 6,557,552; 6,516,796; 6,501,052 in view of Rabinowitz et al (US20040202617). Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims would have been obvious over the reference claims in view of Rabinowitz et al (US20040202617). See discussions above.

Claims **15-16, 19, 23-30** are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 16-18, 24-32 of copending Application No. 10/958,329 (US 20050079137). Although the conflicting

claims are not identical, they are not patentably distinct from each other because the instant claims would have been obvious over the reference claims. Here, both the instant claims and the reference claims are drawn to a method of generating an aerosol comprising supplying a liquid aerosol formulation to a flow passage and heating the liquid to form a vapor. The active agents suitable for the said method are "a thermally stable active agent". The difference between the two applications is that in the instant claims, the active agent is buprenorphine while in the reference claims the active agent is scopolamine. It is considered that the method of generating vapors would be applicable to any "thermally stable active agent" and that substituting one agent for the other would have been obvious to one of ordinary skill in that art. It is also considered that the various "thermally stable active agents" are obvious variations of each other and substituting one for another does not alter the scope of claims. This was also apparent from the election of species requirement.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims **15-16, 19, 23-30** are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 19-28 and 32-34 of copending Application No. 10/654,980 (US 20040079368) in view of Rabinowitz et al (US20040202617). Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims would have been obvious over the reference claims. Here, both the instant claims and the reference claims are

drawn to a method of generating an aerosol comprising supplying a liquid aerosol formulation to a flow passage and heating the liquid to form a vapor. The active agents suitable for the said method are "a thermally stable active agent". The difference between the two applications is that in the instant claims, the active agent is buprenorphine while the reference claims recite a liquid source. Rabinowitz teaches delivery of drugs through an inhalation route. Specifically, an aerosol containing active agents that are used in inhalation therapy is disclosed. Also a method of delivery is disclosed which method comprises heating a thin layer of an active agent, on a solid support, to from a vapor, and passing air through the heated vapor to produce aerosol particles having less than 5% degradation products. It is disclosed that typically, the aerosol particles have a mass median aerodynamic diameter (MMAD) of less than 5 microns. Preferably the particles have an MMAD of less than 3, less than 2 or less than 1 micron. Suitable active agents for the said aerosol vapor formulation include **buprenorphine** or its salts. The formulations may contain one or more excipients such as propylene glycol, glycerol, ethanol, methanol, etc. It would have been obvious to one of ordinary skill in the art to have looked in the art for suitable active agents for the said vaporizing method.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims **15-16, 19, 23-30** are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 32-50 and 59-65

of copending Application No. 10/654,934 (US 20040081624) in view of Rabinowitz et al (US20040202617). Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims would have been obvious over the reference claims. Here, both the instant claims and the reference claims are drawn to a method of generating an aerosol comprising supplying a liquid aerosol formulation to a flow passage and heating the liquid to form a vapor. The active agents suitable for the said method are "a thermally stable active agent". The difference between the two applications is that in the instant claims, the active agent is buprenorphine while the reference claims recite a liquid formulation and recite various possible classes of drugs. Rabinowitz teaches delivery of drugs through an inhalation route. Specifically, an aerosol containing active agents that are used in inhalation therapy is disclosed. Also a method of delivery is disclosed which method comprises heating a thin layer of an active agent, on a solid support, to from a vapor, and passing air through the heated vapor to produce aerosol particles having less than 5% degradation products. It is disclosed that typically, the aerosol particles have a mass median aerodynamic diameter (MMAD) of less than 5 microns. Preferably the particles have an MMAD of less than 3, less than 2 or less than 1 micron. Suitable active agents for the said aerosol vapor formulation include **buprenorphine** or its salts. The formulations may contain one or more excipients such as propylene glycol, glycerol, ethanol, methanol, etc. It would have been obvious to one of ordinary skill in the art to have looked in the art for suitable active agents for the said vaporizing method.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims **15-16, 19, 23-30** are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims of copending Application Nos. 10/655,017 (US 20040129793); 10/795,522 (US 20040170405); 10/732,646 (US 20050126624); 10/952,434 (US 20050133029); 10/871,536 (US 20050143866); 11/140,984 (US 20050205084) in view of Rabinowitz et al (US20040202617). Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims would have been obvious over the reference claims. Here, both the instant claims and the reference claims are drawn to a method of generating an aerosol comprising supplying a liquid aerosol formulation to a flow passage and heating the liquid to form a vapor. The active agents suitable for the said method are "a thermally stable active agent". The difference between the two applications is that in the instant claims, the active agent is buprenorphine while the reference claims recite a liquid source or a fluid formulation. Rabinowitz teaches delivery of drugs through an inhalation route. Specifically, an aerosol containing active agents that are used in inhalation therapy is disclosed. Also a method of delivery is disclosed which method comprises heating a thin layer of an active agent, on a solid support, to from a vapor, and passing air through the heated vapor to produce aerosol particles having less than 5% degradation products. It is disclosed that typically, the aerosol particles have a mass median aerodynamic

diameter (MMAD) of less than 5 microns. Preferably the particles have an MMAD of less than 3, less than 2 or less than 1 micron. Suitable active agents for the said aerosol vapor formulation include **buprenorphine** or its salts. The formulations may contain one or more excipients such as propylene glycol, glycerol, ethanol, methanol, etc. It would have been obvious to one of ordinary skill in the art to have looked in the art for suitable active agents for the said vaporizing method.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims **15-16, 19, 23-30** are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 9-20 of 10/830,463 (US 20040223918) and claims 32-50 of copending Application No. 10/829,945 (US 20040223917) in view of Rabinowitz et al (US20040202617). Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims would have been obvious over the reference claims. Here, both the instant claims and the reference claims are drawn to a method of generating an aerosol comprising supplying a liquid aerosol formulation to a flow passage and heating the liquid to form a vapor. The active agents suitable for the said method are "a thermally stable active agent". The difference between the two applications is that in the instant claims, the active agent is buprenorphine while the reference claims recite cromolyn sodium and insulin respectively. Rabinowitz teaches delivery of drugs through an inhalation route. Specifically, an aerosol containing active agents that are used in

inhalation therapy is disclosed. Also a method of delivery is disclosed which method comprises heating a thin layer of an active agent, on a solid support, to from a vapor, and passing air through the heated vapor to produce aerosol particles having less than 5% degradation products. It is disclosed that typically, the aerosol particles have a mass median aerodynamic diameter (MMAD) of less than 5 microns. Preferably the particles have an MMAD of less than 3, less than 2 or less than 1 micron. Suitable active agents for the said aerosol vapor formulation include **buprenorphine** or its salts. The formulations may contain one or more excipients such as propylene glycol, glycerol, ethanol, methanol, etc. It would have been obvious to one of ordinary skill in the art to have looked in the art for suitable active agents for the said vaporizing method.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

Applicant's arguments with respect to claims 1-30 have been considered but are moot in view of the new ground(s) of rejection. However arguments with regard to the rejection of claim 26 under 35 USC 112, second paragraph will be responded to.

Applicant argues that indefiniteness has not been established and that examiner has not factually established that one of ordinary skill in the art would not have been able to ascertain the scope of protection defined by the claim. This is not persuasive because specification does not provide any definition or description of the "derivatives thereof". One of ordinary skill in the art would not be able to determine the scope of

"derivatives" without any direction from the specification. In other words lack of any guidance in the specification would impose undue experimentation on those of ordinary skilled in the art to determine which derivatives would be suitable. Also due to the lack of adequate disclosure in the specification, the metes and bounds of the claim would be undetermined.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

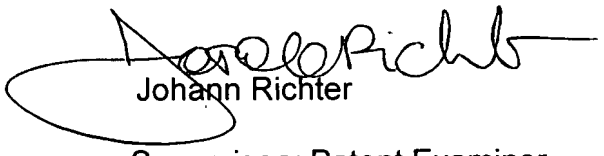
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mina Haghighatian whose telephone number is 571-272-0615. The examiner can normally be reached on core office hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Mina Haghighatian

June 11, 2007



Johann Richter

Supervisory Patent Examiner

Technology Center 1600